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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,845	09/24/1999	MARIN JANUSZ	AAT-11612	1703

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EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/269,845	JANUSZ ET AL.
	Examiner	Art Unit
	Roy Teller	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,16,24,26-32,35,40,41,54 and 58-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16,24,26-32,35,40,41,54 and 58-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

This office action is in response to the amendment, received 8/7/03, in which applicant amended claims 15, 24, 27 and 31, and have added new claims 58-68.

Claims 15, 16, 24, 26-32, 35, 40, 41, 54, and 58-68 are pending.

Claim Rejections - 35 USC § 112

Claims 15, 16, 24, 26-32, and 35stand rejected under 35 U.S.C. 112, first paragraph for the reasons set forth in the previous office action.

Applicant's arguments were carefully considered but were not found persuasive.

Claims 15, 16, 24, 26-32 and 35 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for colostrinin usage as a modest cytokine inducer in human leukocytes does not reasonably provide enablement for treatment of dementia, or Alzheimer's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant contends that the specification discloses that Colostrinin can be administered to human patients to treat dementia, applicant points to example IX in the instant specification, which refers to "improvement of contact" in patients treated with Colostrinin. Applicant is arguing features which are not claimed. While the claims are interpreted in light of the teachings of the specification, limitations from the specification are not read into the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54, and 58-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 54, and 58-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for colostrinin usage as a modest cytokine inducer in human leukocytes does not reasonably provide enablement for treatment of dementia, neurodegenerative diseases or Alzheimer's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard , the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1998) as to undue experimentation.

The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention:

Colostrinin is used as a medicament and treatment for dementia,

and Alzheimer's disease.

The state of the prior art and the predictability or lack thereof in the art:

In Inglot (Archivum Immunologiae et Therapiae experimentalis, 1996, vol. 44, pp. 215-224) cited in paper NO: 7, colostrinine is referred to as a modest cytokine inducer in human leukocytes, see title and abstract. In Janusz (Archivum Immunologiae et Therapiae experimentalis, 1993, vol. 41, pp. 275-279) cited in paper NO: 19, ovine colostrum is an immunomodulatory peptide. Treatment for dementia, and Alzheimer's disease were not investigated. The prior art cited above does not teach of a treatment for dementia, and Alzheimer's disease, therefore, undue experimentation would be necessary to determine a treatment for dementia, and Alzheimer's disease involving colostrinin.

The specification has shown an immunomodulation effect occurred when colostrinin was administered to mice and humans. The specification did not show and effect and/or treatment for dementia, neurodegenerative diseases and Alzheimer's disease. The art is still unpredictable in light of Kruzel's (Journal of Molecular Neuroscience, 2001, vol. 17, pp. 379-389)cited in paper NO: 19, abstract which stated"...it is hoped that the beneficial use of colostrinin in Alzheimer's disease...will revive interest in its clinical application for treatment and/or prophylaxis of many age-related disorders."

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991).

The specification showed some guidance with regards to an immunomodulation effect when colostrinin was administered to mice and humans. The specification gave little guidance or direction in the treatment of dementia, and Alzheimer's disease. In example IX, pages 19-20 of the instant specification, a method of treatment for early and moderate stages of Alzheimer's

disease was investigated. It was found that colostrinin treatment induced a state of hyporeactivity or tolerance.In example X, page 21 of the instant specification, a method of treatment for early and moderate stages of Alzheimer's disease was investigated. It was found that colostrinin treatment induced a state of hyporeactivity or tolerance. Beyond this, no treatment of dementia, or Alzheimer's disease occurred.

The instant specification gave examples of inducted cytokines with colostrinin *in vitro* on blood taken from healthy and sick volunteers. Patients with early stages of Alzheimer's disease were given Colostrinin/NP tablets in which improved contact and uplift of mood was observed. Alzheimer's disease can only be diagnosed post-mortem with the dissection of the brain. The examples IX and X, pages 19-21 of the instant specification, are not adequate working examples for the treatment of dementia, or Alzheimer's disease.

The breadth of the claims and the quantity of experimentation needed:

Undue experimentation would be necessary in order to determine a treatment for dementia, or Alzheimer's disease involving colostrinin.

In consideration of each of the above factors, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosures, examples, teachings and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more th... ...ear prior to the date of application for patent in the United States.

Claims 40, 41 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Burrin (Pediatric Research, vol. 37, pp-593-599, 1995).

Burrin teaches nutrient-independent and nutrient-dependent factors stimulate protein synthesis in colostrum-fed newborn pigs, see title. Burrin discloses neonatal pigs fed mature milk, colostrum, or a formula containing a macronutrient composition comparable to that of colostrum for 24 hours, see abstract. The rates of protein synthesis in several tissues measured after 24 hours of feeding were greater than those reported previously after 6 hours of feeding, see abstract. The acute stimulation of protein syntheisi in visceral and skeletal muscle tissues of neonatal pigs fed milk, colostrum, or formula was primarily influenced by nutrient intake and associated with rapid secretion of insulin, see abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 40, 41, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrin (Pediatric Research, vol. 37, pp-593-599, 1995).

The instant invention is drawn to a dietary supplement comprising a therapeutic unit of colostrinin.

Burrin teaches nutrient-independent and nutrient-dependent factors stimulate protein synthesis in colostrum-fed newborn pigs, see title. Burrin discloses neonatal pigs fed mature milk, colostrum, or a formula containing a macronutrient composition comparable to that of colostrum for 24 hours, see abstract. The rates of protein synthesis in several tissues measured after 24 hours of feeding were greater than those reported previously after 6 hours of feeding, see abstract. The acute stimulation of protein syntheisi in visceral and skeletal muscle tissues of neonatal pigs fed milk, colostrum, or formula was primarily influenced by nutrient intake and associated with rapid secretion of insulin, see abstract.

It would have been *prima facia* obvious to use the teachings of Burrin to arrive at the instant invention because Burrin's discloses a novel, specific stimulation of skeletal muscle and jejunal protein synthesis in colstrum-fed pigs, see abstract.

Conclusion

All claims are rejected.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703)305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

RT
1654
10/31/03

RT

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